UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,704	06/05/2000	Ralph M. Steinman	RUJ-001CNRCE2	7559

959 7590 04/13/2011

NELSON MULLINS RILEY & SCARBOROUGH LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
04/13/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/586,704
Filing Date: June 05, 2000
Appellant(s): STEINMAN ET AL.

Jill Gorny Sloper
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/23/11 appealing from the Office action mailed 4/27/10.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal: US 09/925284.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application: Claims 26-28,35,36,38-40,42,43 are rejected. Claims 22,23,29,30 were withdrawn from consideration as directed to nonelected inventions.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(**5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The previously pending rejections of claims 44,45 have been rendered moot in view of the cancellation of said claims as per the amendment of 1/25/11 which has been entered.

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

Schjetne et al., "Delivery of Antigen to CD40 Induces Protective Immune Responses Against Tumors", J. of Immunol., vol 178 (2007), pages 4169-76.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 26-28,35,36,38,39,40,42,43 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the appellant had possession at the time of invention of the conjugate recited in the claimed composition.

The instant claims recite use of an anti-DEC antibody which binds human DEC-205. The term human DEC-205 would appear to encompass full length human DEC-

205 as well as mutants and variants or alleles of said human protein (for example see specification, page 28). However, only full length murine DEC-205 protein is disclosed in the specification of the parent application. The sequence listing discloses two peptides derived from human DEC 205 of 30 and 25 amino acids respectively. However, human DEC-205 contains approximately 1800 amino acids. There is no disclosure in the specification of the identity of the approximately 1750 other amino acids or purified human DEC-205. Regarding appellants comments about claims 35,36,38,39, said claims recite use of an antihuman DEC 205 antibody which binds an amino acid seqeunce "as set forth" in SEQ. ID. No. 1 and wherein said language is interpreted as equivalent in scope to comprising. Therefore said claim could be interpreted as encompassing antibodies which bound the seqeunce comprising said amino acid sequence wherein said sequence would encompass full length human DEC-205.

Thus, whilst the specification of discloses murine DEC-205 protein, the term human DEC-205 would appear to encompass full length human DEC-205 and undescribed mutants and variants or alleles of said human protein. Thus, the claims would encompass use of antibodies which bound full length human DEC-205 as well as undescribed mutants and variants or alleles of human DEC-205. Regarding claim 40, in the absence of human DEC-205, it would not be possible to establish which antibodies reacted with human DEC-205.

In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated:

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will

hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

2. Claims 26-28,35,36,38,39 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification for the recitation of “human DEC-205 protein comprising an amino acid sequence as set forth in SEQ ID 1" in claim 26/35. Whilst the specification discloses SEQ ID NO 1 as a peptide derived from DEC 205, there is no disclosure in the specification as originally filed of a DEC-205 protein comprising said peptide wherein the molecule could have any amino acids in association with the aforementioned sequences recited in the claim. There is no written description in the specification as originally filed for the scope of the claimed invention (e.g. the claimed invention constitutes new matter). Regarding the various cited

passages of the specification, none of the passages disclose human DEC-205 protein comprising an amino acid sequence as set forth in SEQ ID 1 in claim 26/35. Whilst the specification discloses SEQ ID NO 1 as a peptide derived from DEC 205, there is no disclosure in the specification as originally filed of a DEC-205 protein comprising said peptide wherein the molecule could have any other amino acids in association with the aforementioned sequences recited in the claim.

There is no written description of the scope of the claimed invention in the specification as originally filed (aka the claimed inventions constitute new matter).

3. Claims 26-28,35,36,38,39,40,42,43 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed vaccine. The specification does not disclose how to use the instant invention for the in vivo treatment or prevention of disease in humans. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment/prevention of disease in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence

as to how the instant invention could be used for the in vivo treatment/prevention of disease in humans.

Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . . 35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a

claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

Regarding Wands factors 4,5,7,8, the instant invention deals with a vaccine for use in humans. Schjetne et al. disclose that DEC205 antigen conjugates administered in vivo require CD40 ligation in vivo in order to induce an immune response (see page 4169, second column, first paragraph). Thus, the claimed invention would not be

expected to induce an immune response because it lacks an agent that causes CD40 ligation. Thus, said invention could not be used to treat disease in human because it does not induce an immune response. Regarding the use of the instant invention as a tumor vaccine, Schjetne et al. discloses that even in the presence of CD40 ligation, that tumor vaccines would be unsuitable for treating tumor bearing animals (see page 4175, first page, last paragraph). The claims encompass a vaccine for treating tumor bearing animals/humans. Furthermore, there is currently no known tumor vaccine that can be used to treat cancer in humans wherein the vaccine utilizes tumor antigens.
As per Wands factor (8), the claims encompass the treatment of disease in humans.

Regarding Wands factors 1-3, there is no disclosure in the specification of any in vivo evidence in any model wherein the claimed invention is used as a vaccine or tumor vaccine. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.).

It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

(10) Response to Argument

1) Claims 26-28,35,36,38,39,40,42,43 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding appellants comments and the Nussenzweig declaration, the cloned human DEC-205 sequence referred to i**s not disclosed in the specification of the instant application or parent applications**. Regarding the amended claims, human DEC-205 is approximately 1800 amino acids in length. The recitation in the claim of a 30 or 25 amino acid sequence derived from said molecule in itself does not provide written description of a molecule that is almost 1800 amino acids in length. The claims encompass use of antibodies which bind any immunogenic epitope on the approximately 1775 undisclosed amino acids of DEC 205 and the specification does not disclose the identity of said amino acids or disclose purified human DEC-205 protein.

Regarding appellants comments, the US CAFC ruled in In Re Wallach et al. (CAFC 03-1327, available on the CAFC website) that written description for a nucleic acid sequence encoding a protein required a complete intact nucleic acid sequence encoding said protein or a complete intact amino acid sequence of a protein (from which the nucleic acid sequence could be derived). The court ruled that a partial amino acid sequence in itself (from which nucleic acid information could be derived) was insufficient

to provide written description for the claimed nucleic acid. In the instant application, the claims encompass antibodies which bind human DEC-205 for which no complete amino acid sequence has been furnished. As the MPEP explains, "disclosure of a partial structure without additional characterization of the product may not be sufficient to evidence possession of the claimed invention." MPEP § 2163. In Amgen v. Chugai, the CAFC expounded:

A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound require that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property .... because an alleged conception having no more specificity than that is simply a wish to know The identity of any material with that biological property. 927 F.2d at 1206. Without that sequence, however, or with only a partial sequence, those structures cannot be determined and the written description requirement is consequently not met.

Regarding Figure 6 in parent application 09/586704 (and the reference to said Figure in pages 10 and 56 of the specification), said Figure refers to experiments performed in mice, not humans. Regarding claims 40,42,43, said claims still require use of human

DEC-205 to determine if the antibodies cross react with human DEC-205 (aka they recite that the antibody binds human DEC-205). It is noted that all of the experimental data actually disclosed in the specification involves murine DEC-205.

Regarding appellants comments about isolating human DEC-205 (wherein isolated human DEC-205 is not disclosed in the specification), attention is directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated:

The description requirement of the patent statute requires a description of an invention**, not an indication of a result that one might achieve if one made that invention.** See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Regarding appellants comments about Capon v. Eshhar (CAFC August, 2005), the invention under consideration in said case was a conjugate that used two *known* components. The invention was the conjugate, not the components. The components of the conjugate (scFv and transmembrane/cytoplasmic domain of a portion that triggers cell activation) were well known in the art. Thus, their invention was a conjugate using components well known in the art. Thus, said decision is not relevant

to the claims under consideration wherein Human DEC-205 was not known in the art (it had not been isolated or sequenced).

Regarding appellants comments about claims 35,36,38,39, said claims recite use of an antihuman DEC 205 antibody which binds an amino acid seqeunce "as set forth" in SEQ. ID. No. 1 and wherein said language is interpreted as equivalent in scope to comprising. Therefore said claim could be interpreted as encompassing antibodies which bound the seqeunce comprising said amino acid sequence wherein said sequence is present in intact human DEC-205. Regarding claim 40, in the absence of human DEC-205, it would not be possible to establish which antibodies reacted with human DEC-205. Furthermore, there is no disclosure in the specification of a monoclonal antibody which binds murine DEC-205 and also binds human DEC-205. Whilst the specification refers to a polyclonal antisera with such a property, there is no disclosure in the specification that such an antibody was actually made. In the absence of a demonstration in the specification that such an antibody was actually made, written description of such an antibody is lacking. Furthermore, the claims encompass monoclonal antibodies which bind particular epitopes on both murine and human DEC-205 wherein there is no disclosure of such antibodies in the specification or identification of the amino acid sequence of such epitopes.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984)

(affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

2) . Claims 26-28,35,36,38,39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding appellants comments, there is no support in the specification as originally filed for the recitation of “human DEC-205 protein comprising an amino acid sequence as set forth in SEQ ID 1” in claim 26/35. Whilst the specification discloses SEQ ID NO 1 as a peptide derived from a DEC 205, there is no disclosure in the specification as originally filed of a DEC-205 protein comprising said peptide wherein the molecule could have any amino acids in association with the aforementioned

sequences recited in the claim. There is no written description in the specification as originally filed for the scope of the claimed invention (e.g. the claimed invention constitutes new matter). Regarding the various cited passages of the specification, none of the passages disclose human DEC-205 protein comprising an amino acid sequence as set forth in SEQ ID 1 in claim 26/35. Whilst the specification discloses SEQ ID NO 1 was a peptide derived from DEC 205, there is no disclosure in the specification as originally filed of a DEC-205 protein comprising said peptide wherein the molecule could have any other amino acids in association with the aforementioned sequences recited in the claim.

Regarding appellants comments, as per the previous Office Action, "There is no written description of the scope of the claimed invention in the specification as originally filed (aka the claimed inventions *constitute new matter*).". The Examiner did erroneously refer to SEQ ID No 1 as No 7 in the previous Office Action. The MPEP section 2163 states:

2163.01 Support for the Claimed Subject Matter in Disclosure

A written description requirement issue generally involves the question of whether the subject matter of a claim is supported by [conforms to] the disclosure of an application as filed. If the examiner concludes that the claimed subject matter is not supported [described] in an application as filed, this would result in a rejection of the claim on the ground of a lack of written description under 35 U.S.C. 112, first paragraph or denial of the benefit of the filing date of a previously filed application. The claim should not be

rejected or objected to on the ground of new matter. As framed by the court in In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981), the concept of new matter is properly employed as a basis for objection to amendments to the abstract, specification or drawings attempting to add new disclosure to that originally presented. While the test or analysis of description requirement and new matter issues is the same, the examining procedure and statutory basis for addressing these issues differ. See MPEP § 2163.06.

Whilst the specification discloses SEQ ID NO 1 was a peptide derived from DEC 205, there is no disclosure in the specification as originally filed of a DEC-205 protein comprising said peptide wherein the molecule could have any other amino acids in association with the aforementioned sequences recited in the claim and still constitute a DEC-205 protein. For example, the specification discloses on page 3 that the human DEC-205 protein can contain SEQ ID NO 1, but will also have all of the other properties disclosed in page 3 of the specification. Thus, the specification discloses SEQ ID NO 1 was a peptide derived from DEC 205, there is no disclosure in the specification as originally filed of a DEC-205 protein comprising said peptide wherein the molecule could have any other amino acids in association with the aforementioned sequences recited in the claim and still constitute a DEC-205 protein.

3) Claims 26-28,35,36,38-40,42,43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding appellants comments and Wands factors 4,5,7,8, the instant invention deals with a vaccine for use in humans. Schjetne et al. disclose that DEC205 antigen conjugates administered in vivo require CD40 ligation in vivo in order to induce an immune response (see page 4169, second column, first paragraph). Thus, the claimed invention would not be expected to induce an immune response because it lacks an agent that causes CD40 ligation. Thus, said invention could not be used to treat disease in human because it does not induce an immune response. Regarding the use of the instant invention as a tumor vaccine, Schjetne et al. discloses that even in the presence of CD40 ligation, that tumor vaccines would be unsuitable for treating tumor bearing animals (see page 4175, first page, last paragraph). The claims encompass a vaccine for treating tumor bearing animals/humans. Furthermore, there is currently no known tumor vaccine that can be used to treat cancer in humans wherein the vaccine utilizes tumor antigens. As per Wands factor (8), the claims encompass the treatment of disease in humans. Regarding Wands factors 1-3, there is no disclosure in the specification of any in vivo evidence in any model wherein the claimed invention is used as a vaccine or tumor vaccine. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.). It appears that undue experimentation would be required of one skilled in the art

to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

Regarding appellants comments, the MPEP section 2164.01(c) states:

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (claiming a chimeric gene capable of being expressed in any cyanobacterium and thus defining the claimed gene by its use).

The claims under consideration are all vaccines wherein vaccines are used for the treatment/prevention of human disease.

Regarding appellants comments, the quoted passage of Schjetne et al. refers to ***physical linkage of antiCD40 antibody and antigen***. It does not disclose that antiCD40 ligation is not required for antigen activation (aka it discloses that in certain circumstances the ligating antibody whilst required need not be attached to the antigen). ***Schjetne et al. disclose that DEC205 antigen conjugates administered in vivo require CD40 ligation in vivo in order to induce an immune response (see page 4169, second column, first paragraph)***.

Schjetne et al., page 4169, second column, first paragraph, teach:

"Recently, the importance of activating DC via CD40 ligation was demonstrated in a series of studies, where DEC205-targeted Ab-Ag fusion proteins induced tolerance to the Ag unless an agonistic anti-CD40 mAb was coadministered (4, 9, 10).".

Thus, the claimed invention would not be expected to induce an immune response because it lacks an agent that causes CD40 ligation. Thus, said invention could not be used to treat disease in human because it does not induce an immune response. Regarding the use of the instant invention as a tumor vaccine, Schjetne et al. discloses that even in the presence of CD40 ligation, that tumor vaccines would be unsuitable for treating tumor bearing animals (see page 4175, first page, last paragraph). The claims encompass a vaccine for treating tumor bearing animals/humans. Furthermore, there is currently no known tumor vaccine that can be used to treat cancer in humans wherein the vaccine utilizes tumor antigens.

Regarding appellants reference to various publications not related to use of the claimed invention, said references do not address the issues raised by Schjetne et al. Appellants reference to publications that are not of record and of which copies have not been submitted are not addressed. Regarding appellants comments about 09/925284, Schjetne et al. disclose that DEC205 antigen conjugates administered in vivo requires CD40 ligation in vivo in order to induce an immune response (see page 4169, second column, first paragraph). The data referred to in 09/925284 is disclosed in the Steinman publications referred to in Schjetne et al. page 4169, second column, first paragraph (aka 4.9,10). Thus, the claimed invention would not be expected to induce an immune response because it lacks an agent that causes CD40 ligation. Thus, said invention could not be used to treat disease in human because it does not induce an immune response. Regarding the use of the instant invention as a tumor vaccine, Schjetne et al.

discloses that even in the presence of CD40 ligation, that tumor vaccines would be unsuitable for treating tumor bearing animals (see page 4175, first page, last paragraph). The claims encompass a vaccine for treating/preventing any tumor bearing animals/humans. Furthermore, there is currently no known tumor vaccine that can be used to treat or to prevent cancer in humans wherein the vaccine utilizes tumor antigens. Furthermore, regarding the mouse data which appellant refers to in the specification, none of the cited experiments involve treatment of any disease in a mouse model. However, as per above, Schjetne et al. discloses that the invention as claimed would be unsuitable as a vaccine for treating disease.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Ron Schwadron/

Primary Examiner, Art Unit 1644

Conferees:

/Phuong N Huynh/

Acting SPE 1644

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1647